JUL - 3 2001

K011114

510(k) SUMMARY

Submitted By:	ETYMOTIC RESEARCH 61 Martin Lane Elk Grove Village, IL 60007
Telephone:	(847)-228-0006
Contact Person:	Erik Gundersen
Name of Device:	Etymotic Research ER-10D OAE Probe.
Common Name	Otoacoustic Emissions Probe.
Classification:	Class II

Description of the Device: The ER-10D OAE Probe has been designed as a replacement of the ER-10B+ AND ER-10C Probe Systems. It offers equivalent performance, improved tip design and ease of use. The new probe consists of the probe head with removable tip, 12 inches of flexible silicon tubing that extends from the probe head to the preamp enclosure and five feet of flexible cable that extends that extends from the preamp enclosure to the mini DIN connector.

One single microphone is housed in the probe head which is connected to to a two conductor shielded cable. The microphone cable runs down one of the three channels in the silicone probe tubing. The other two channels are used for sound delivery up to the probe head. The two receivers are housed in the preamp enclosure which also houses the circuit board and EMI/ESD shield.

The circuit board contains the microphone biasing /equalization circuitry and the receiver equalization circuitry. The EMI/ESD shield wraps around the entire circuit board to help reduce electromagnetic interference and electrostatic discharge. The five foot 8 – conductor shielded cable is connected to the circuit board on one end and has a 8-pin mini DIN connector on the other end.

For users of the Etymotic Research CUB^{e}DIS™ Otoacoustic Emissions Test Instrument there is a connector adapter to permit the replacement of the ER-10B probe with the ER-10D OAE Probe.

Indication: This product is intended for use with Otoacoustic Test Instruments designed to operate with this probe:

1) To evoke or stimulate the generation of distortion product otoacoustic emissions (DPOAEs), utilizing pure tone stimulus presentation, for the purpose of determining the presence of cochlear function.

2) To evoke or stimulate the generation of Transient Evoked Otoacoustic Emissions (TEOAE's), utilizing click sounds.

3) To pick up evoked otoacoustic emissions (OAEs) by means of a tiny microphone built into the probe.

An assortment of eartips for this probe are designed to fit adult, child, and infant ears.

Substantial Equivalency: The Etymotic Research ER-10D OAE Probe with disposable eartips is substantially equivalent to:

The ER-10B Probe and eartips used with the CUB^{e}DIS™ Otoacoustic Emissions Test Instrument that has a cleared 510(k) K930553 (ETYMOTIC RESEARCH, Elk Grove Village, IL 60007). and

ER-10C (CP Version) Probe and eartips used with the CUB^{e}DIS II™ DPOAE Measurement System that has a cleared 510(k) K981460 (MIMOSA ACOUSTICS, Inc., Mountainside, NJ 07092.

Comparison of Similarities and Differences to Predicate Devices:

	ER-10B Probe Submitted as Part of CUB^{e}DIS™ Otoacoustic Emissions Test Instrument (K930553)	ER-10D Probe the Subject of this 510(k) Application
Intended Use.	Identical for	Both Units
Patient Population.	Infants, Children, and Adults	Same
Includes a Switchable Internal Amplifier.	Yes, Switchable. 0 dB, 20dB, 40 dB	Has a Non-Switchable Amplifier
Output Impedence of Preamplifier.	100 Ohms	100 Ohms
Undistorted Output (Maximum Output Voltage of Preamp).	120 dB	Same
Sensitivity of Microphone.	50mV/Pascal (-46 dB re 1 V/μBar): 0dB SPL = 0dBμV.	Same
Frequency Response of Microphone.	+/- 1dB at 1kHz; +/-4dB Between 250 and 8 kHz	+/- 1 dB at 1 kHz, +/- 4dB Between 200 and 12 kHz
Noise Level of Microphone.	0dB SPL in 100Hz Bandwidth	3dB SPL in 100Hz Bandwidth
Diode Circuit to Protect Microphone Circuit from Electrostatic Discharge (ESD).	Yes	Yes
Microphone Cord.	6 ft. Long, 2 Conductor – Miniature, Shielded	6 ft. Long, 8 Conductor, Shielded
Acoustic Polarity of Receivers.	Positive Voltage Gives Positive Acoustic Pressure.	Positive Voltage Gives Positive Acoustic Pressure.
DPOAE Capability. (DPOAE = Distortion Product Otoacoustic Emissions).	Yes	Yes
TEOAE Capability (TEOAE = Transient Evoked Otoacoustic Emissions).	Not Specifically Designed for this Purpose.	Yes
Ear Tip Material	Polyvinyl Chloride	Styrene Block Copolymer
Safety	Ear-tips are Disposable and are labeled for Single Patient Use. The probe, if used as intended, provides electrical isolation with the plastic eartips so that there is no path for electrical conductance to the patient.	Ear-tips are Disposable and are Labeled for Single Patient Use. The probe, if used as intended, provides electrical isolation with the plastic eartips so that there is no path for electrical conductance to the patient.*

	ER-10C (CP Version) Probe Submitted as Part of CUB^{e}DIS™ II DPOAE Measurement System (K981460)	ER-10D Probe the Subject of this 510(k) Application
Intended Use.	Identical for	Both Units
Patient Population.	Infants, Children, and Adults	Same
Designed for both DPOAE and TEOAE Measurements.	No	Yes
Number of Wire Conductors	7	8
Type of Interface Connector	7 Pin Mini DIN Connector	8 Pin Mini DIN Connector
Switchable Amplifier	No	No
Frequency Response of Microphone.	+/- 1dB at 1kHz; +/-4dB between 250 and 8000 Hz	+/- dB at 1 kHz, +/- 4 dB between 200 and 12 kHz
Noise level of Microphone.	0dB SPL in 100Hz Bandwidth	3dB SPL in 100Hz Bandwidth
Diode Circuit to Protect Microphone Circuit from Electrostatic Discharge (ESD).	Yes	Yes
Microphone Cord.	6 ft. Long, 2 Conductor – Miniature, Shielded	6 ft. Long, 8 Conductor, Shielded
Acoustic Polarity of Receivers.	Positive Voltage Gives Positive Acoustic Pressure.	Same
Output Impedance	100 Ohm	100 Ohm
Sound Source Sensitivity	72 dB SPL for 1 V RMS Input	86 dB SPL for 1 V RMS Input
Ear Tip Material	Polyvinyl Chloride	Styrene Block Copolymer
Safety	Ear-tips are disposable and are labeled for Single Patient Use. The probe, if used as intended, provides electrical isolation with the plastic eartips so that there is no path for electrical conductance to the patient.	Ear-tips are disposable and are labeled for Single Patient Use. The probe, if used as intended, provides electrical isolation with the plastic eartips so that there is no electrical conductance to the patient.*

* Please note that the ER-10D Probe ear-tips are identical to those used in our ERO•SCAN™Otoacoustic Test Instruments (K980533 and K010165).

Date on which Summary was Prepared: April 11, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2001

Mr. Erik Gundersen, Engineer
ETYMOTIC RESEARCH, Inc.
61 Martin Lane
Elk Grove Village, IL 60007

Re: K011114
Trade Name: ETYMOTIC RESEARCH ER-10D OAE
Regulation Number: 21 CFR 874.1050
Regulatory Class: Class II
Product Code: 77 EWO
Dated: April 11, 2001
Received: April 12, 2001

Dear Mr. Gundersen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011114

Device Name: Etymotic Research ER-10D OAE Probe

Indications For Use:

This product is intended for use with Otoacoustic Test Instruments designed to operate with this probe:

1) To evoke or stimulate the generation of distortion product otoacoustic emissions (DPOAEs), utilizing pure tone stimulus presentation, for the purpose of determining the presence of cochlear function.

2) To evoke or stimulate the generation of Transient Evoked Otoacoustic Emissions (TEOAE's), utilizing click sounds.

3) To pick up evoked otoacoustic emissions (OAEs) by means of a tiny microphone built into the probe.

An assortment of eartips for this probe are designed to fit adult, child, and infant ears.

The otoacoustic emissions are low-level audio frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing or, at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by simple OAE test.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use JMC 7/3/01
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

JMC 7/3/01
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011114